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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,801	07/21/2006	Gordon Dawson	11123.0108USWO	8782

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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
03/23/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,801	DAWSON ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-16,19,20 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-16,19,20 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/21/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and responses filed 10/4/2011 and 12/08/2010 to the non-final Office action dated 4/7/2010 have been entered. Claims 1-10, 13-16, 19, 20 and 26-32 were amended. Claims 17 and 18 were cancelled. No claims were newly added. Claims 23-25 were withdrawn without traverse on 12/17/2009. Claims 1-10, 13-16, 19, 20 and 26-32 are pending examination.

Withdrawn Claim Rejections - 35 USC § 112

The rejection of claims 5 and 10 under 35 U.S.C. 112, second paragraph has been withdrawn in view of the amendments filed 10/04/2010 removing the range within a range limitation.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 14-16, 19, 20, 26 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Junien et al. (EP 1424070; effective date February 6, 2004), as

disclosed in the Office Action mailed 4/07/2010, pages 3-5. The rejection is maintained for reasons of record.

Applicant's Invention

Applicant claims a tablet comprising particles of metformin and fibrate, wherein the composition comprises at 70-95% by weight metformin and fibrate with 5-30% by weight excipients, wherein said excipient consists of one or more pharmaceutically acceptable excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. Claim 4 and 32 are directed towards the inherent properties of the composition. Claim 16 is directed to intended use.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Junien et al. teach a composition comprising metformin and a PPAR agonist, preferably fenofibrate [0013, 0030; limitation of claim 7]. The term PPAR agonist is equivalent to a PPAR activator [0009; limitation of claim 20]. The metformin is in the range of one to twenty times the mass of the PPAR agonist [0038; limitation of claims 2 and 3]. The formulation may be formulated as a powder which is an admixture of the active with the solid particles [0046]. Dispersants and other excipients may be added [0049]. The dosage may be formulated as a liquid solution, suspension or emulsion or a capsule, **tablet**, powder or lozenge [0047-0050; limitation of claim 1].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Junien et al. do not teach the specific ranges instantly claimed for the amounts of fibrate and metformin to excipients and the weight of the tablet, however Junien does disclose a compositions comprising 10 to about 3000 mg/day of fibrate and metformin (claims 6 and 7) together with excipients (pharmaceutical carrier, claim 1), and in view of In re Aller, Lacey, and Hall, 105 USPQ 233 (C.C.P.A. 1955), "change in concentration is not patentable modification, however, such changes may impart patentability to process if ranges claimed produce new and unexpected results". Since, the present invention is utilized for the same purpose and applicant has not demonstrated unexpected results the present claims are prima facie obvious.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to utilize the teachings of Junien et al. adjust the ingredients into compositions comprising 5-30% by weight excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. One of ordinary skill would be able to utilize the teachings to formulate different formulations of the metformin and fibrate with excipients with a reasonable expectation of success since adjusting the amounts of excipients to formulate different drug formulations is routine in the art. Furthermore,

adjusting the weight of a tablet to 500-1500 mg would be routine, because such falls in the same range taught by Junien.

Response to Arguments

Applicant's arguments filed 12/08/2010 have been fully considered but they are not persuasive.

First, Applicant argues Junien does not disclose any examples of formulations and only gives examples of co-administration by gavage only, not tablets. The Examiner is has noted this, however the rejection is based on obviousness not anticipation. Although specific examples reciting the instantly claimed ranges are not disclosed, Junien teaches formulating tablet formulations 10 to about 3000 mg/day of fibrate and metformin (claims 6 and 7) together with excipients. Hence, it would have been prima facie obvious to formulate tablets with a reasonable expectation of success.

Applicant argues that to combine a hydrophilic active ingredient, such as metformin, with a hydrophobic ingredient, fibrate, is difficult and requires a high amount of excipients to maintain a high dissolution rate and certain ingredients to aid in compressability. The Examiner is not convinced by this argument because the issues are not substantive to the present claims which are drawn to a composition, not a method of improving dissolution. Junien teaches the required components with specific concentrations of actives and carrier. Therefore to alter the concentration of the components would have been prima facie obvious. Absent a showing of unexpected results from formulating a tablet with metformin, fenofibrate, dispersion aids and excipients the present claim would have been prima facie obvious in view of Junien.

Applicant argues that one skilled in the art would have been led by the prior teachings in the art to use large amounts of excipients, not less than 50% excipients. The Examiner is not persuaded by this argument because there is no teaching in Junien directed to large amounts of excipients, which include greater than 50%. Since, there is not teaching away from formulating compositions having less than 50% it would have been within the skill of one in the art to adjust the excipient range.

Applicant finally argues that metformin acts as a carrier and which allows for the manufacture of tablets with low excipient content and better bioavailability. The Examiner in not persuaded by this argument. The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. Moreover, the combination of fibrate and metformin is specifically taught by Junien, thus there is no requirement to justify their combination.

Claims 6, 8-10, 13 and 27-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Junien et al. (EP 1424070; effective date February 6, 2004), as applied to claims 1-5, 7, 14-16, 19, 20, 26 and 32 above, in view of Stamm et al. (US 6,531,158;

effective date March 11, 2003), as disclosed in the Office Action mailed 4/07/2010, pages 5-7.

Applicant's Invention

Applicant claims a composition comprising particles of metformin and fibrate, wherein the composition comprises at 70-95% by weight metformin and fibrate with 5-30% by weight excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. Claim 6 specifies the fibrate is crystalline or amorphous. Claim 8 specifies the fibrate is micronized or co-micronized. Claim 9 specifies the fibrate is co-micronized with a surfactant. Claim 10 specifies the fibrate has an average particle size of less than 20um. Claims 13 and 28-31 specify the fibrate is in the form of nanoparticles having an average size of about 2000nm to about 100nm. Claim 27 specifies the fibrate has an average particle size of less than 10um.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Junien et al. addressed in the above 103 rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Junien et al. do not teach the fibrate is crystalline or amorphous. Neither is the fibrate taught as being co-micronized. The average particle size of less than 20 or 10um is not taught. It is for this reason that Stamm et al. is joined.

Stamm et al. teach a fenofibrate composition which has high bioavailablility and a method of preparing it (abstract). Since fenofibrate is poorly absorbed in the digestive tract there is a need to improve its bioavailability (column 1, lines 26-29). The fenofibrate is micronized to a size of less than 20um or 10 um (column 3, lines 13-20, 46-48; limitation of claims 10, 13 and 27-31). The preferred surfactant, sodium laurylsulfate, is co-micronized with fenofibrate. (column 4, lines 38 and 39; limitation of claims 8 and 9). The fenofibrate particles granulated are crystalline (column 5, lines 58-67; limitation of claim 6).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Junien et al. and Stamm et al. to utilize fenofibrate which is crystalline, has an average particle size of less than 20 or 10um which is co-micronized in a surfactant because Stamm et al. teaches that fenofibrate granulated with these properties has a higher bioavailability. Hence, it would have been obvious to utilize the teachings of Stamm et al. to include fenofibrate with the above properties in order to improve the absorption of the drug in the digestive tract.

Response to Arguments

Applicant's arguments filed 12/08/2010 have been fully considered but they are not persuasive.

Applicant arguments have been addressed in the above response to arguments.

Thus, the rejections are maintained for reasons of record and the preceding commentary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE SULLIVAN whose telephone number is (571)270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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